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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,292	03/21/2001	Borge Kringelum	030307- 0197	1783

22428 7590 11/05/2003

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,292	KRINGELUM ET AL.	
	Examin r	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Applicant's amendment filed August 8, 2003 has been received and entered into the case. Claims 1 – 26 remain pending and considered. All arguments have been fully considered.

Claim Objections

Claim objections have been withdrawn due to amendment.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 – 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4, 5, 8, 9, 10, 12, 19, and their dependents lack antecedent basis for reciting "the stock inoculum material".

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 - 7, 11, 17 – 22, 24 - 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing.

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

i) providing an inoculum material comprising a concentrate of starter culture cells,

ii) concentrating the inoculum material

iii) dividing the concentrated inoculum material into subsets,

iv) inoculating a subset of the inoculum material by direct, one step inoculation, into a cultivation medium

v) propagating the subset cells for a time sufficient to produce a desired amount of cells, and

vi) harvesting the propagated cells to obtain a starter culture,

wherein when steps (iv) – (vi) are repeated with another subset of cells, the cultures have a consistent quality. The stock inoculum of step i) is a quantity sufficient to inoculate at least

50,000 liters of culture medium or at least 10^8 CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are

named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

6. Claims 1 – 7, 11, 17 – 22 and 24 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Czulak.

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

i) providing an inoculum material comprising a concentrate of starter culture cells,

ii) concentrating the inoculum material

iii) dividing the concentrated inoculum material into subsets,

iv) inoculating a subset of the inoculum material by direct, one step inoculation, into a cultivation medium

v) propagating the subset cells for a time sufficient to produce a desired amount of cells, and

vi) harvesting the propagated cells to obtain a starter culture,

wherein when steps (iv) – (vi) are repeated with another subset of cells, the cultures have a consistent quality. The stock inoculum of step i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium or at least 10^8 CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces

desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the culture medium comprising skimmed milk. However, Czulak teaches a method of inoculating milk with a fat content of 0.3 -- 1.5% (part skim and low fat milk) to produce cheese (abstract). Czulak teaches that use of skim milk enables a cheese product to be made with a substantially reduced fat content (col.1 line 10-15). At the time of the

claimed invention, one of ordinary skill in the art would have been motivated by Czulak to use a culture medium including at least part skim milk in the method of Sing with a reasonable expectation of success for obtaining a dairy product with a reduced fat content.

The above references do not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

7. Claims 1 – 11, 17 – 22 and 24 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Lizak..

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

i) providing an inoculum material comprising a concentrate of starter culture cells,

ii) concentrating the inoculum material

iii) dividing the concentrated inoculum material into subsets,

iv) inoculating a subset of the inoculum material by direct, one step inoculation, into a cultivation medium

v) propagating the subset cells for a time sufficient to produce a desired amount of cells, and

vi) harvesting the propagated cells to obtain a starter culture,

wherein when steps (iv) – (vi) are repeated with another subset of cells, the cultures have a consistent quality. The stock inoculum of step i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium or at least 10^8 CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum material or subset is liquid, frozen, or dried; the frozen inoculums are first thawed before inoculation; and the subsets is combined with an aqueous medium to obtain a suspension before cultivating. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a

culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the methods wherein the inoculums are liquid, frozen or dried; wherein a frozen inoculum is thawed and a dried subset is combined with an aqueous medium before inoculating into the culture medium. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to do so as a matter of routine practice. In support, Lizak teaches conventional storage of starting cultures includes liquid culture, frozen culture and dried culture (col.6 line 53-59). Although Lizak does not specifically teach frozen cultures are thawed and dried cultures are suspended in a liquid medium before inoculation, it was well known in the art to do so at the time of the invention. Therefore,

at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain stock inoculum and/or subset cultures as a liquid, frozen or dried, thaw it and/or suspend the dried culture in a liquid medium because it was routine in the art as demonstrated by Lizak.

The references do not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

8. Claims 1 – 7, 11 – 22 and 24 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Vandenbergh and Matsumiya..

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

i) providing an inoculum material comprising a concentrate of starter culture cells,

ii) concentrating the inoculum material

iii) dividing the concentrated inoculum material into subsets,

iv) inoculating a subset of the inoculum material by direct, one step inoculation, into a cultivation medium

v) propagating the subset cells for a time sufficient to produce a desired amount of cells, and

vi) harvesting the propagated cells to obtain a starter culture,

wherein when steps (iv) – (vi) are repeated with another subset of cells, the cultures have a consistent quality. The stock inoculum of step i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium or at least 10^8 CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum is supplied in a sealed enclosure, made from a flexible material selected from polyolefin, substituted olefin, copolymer of ethylene, polypropylene, polyethylene, polyester, polycarbonate, polyamide, acrylonitrile and a cellulose derivative; a metal foil; has a content of at least 0.01 liters; has an outlet for connecting to the culture medium container, which allows for aseptic inoculation. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach that the stock inoculum is provided in a sealed enclosure as claimed. However, Vandenbergh teaches starter cultures can be stored in leak-proof containers such as a plastic bag, plastic container, metal foil, or sealable containers (col.4 line 30-40). While Vandengergh does not teach the material used or size of such contaniers, Matsumiya discloses cell culture containers made from ethylene copolymers, polyethylene, polypropylene, acrylonitrile copolymers (col.1 line 30-37). In addition, Matsumiya teaches that the flexible, bag

like structures have an inlet tube and an outlet tube with a coupler at its end (col.1 line 23-30). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to provide a stock inoculum in a sealed enclosure because it was well known in the art to do so as demonstrated by Vandengergh and Maysumiya. Furthermore, it would have been well within the purview of one of ordinary skill in the art to optimize the capacity of such containers to correspond with volume of the culture as a matter of routine practice.

The references do not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

9. Claims 1 – 7, 11, 17 – 22 and 24 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Czulak and Lizak..

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

i) providing an inoculum material comprising a concentrate of starter culture cells,

ii) concentrating the inoculum material

iii) dividing the concentrated inoculum material into subsets,

iv) inoculating a subset of the inoculum material by direct, one step inoculation, into a cultivation medium

v) propagating the subset cells for a time sufficient to produce a desired amount of cells, and

vi) harvesting the propagated cells to obtain a starter culture,

wherein when steps (iv) -- (vi) are repeated with another subset of cells, the cultures have a consistent quality. The stock inoculum of step i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium or at least 10^8 CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the

amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Sing does not teach the method wherein each of the named organisms are used. However, at the time of the claimed invention, each of the claimed organisms were well known and used in the art as sources of starter cultures. In support, Czulak teaches a method of inoculating milk with Lactobacillus and Streptococcus cultures whereby the cultures produce a desired cheese flavor (abstract). In further support, Lizak teaches starter cultures of fungus, Bacillus, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated by routine practice to use the above named microorganisms in the method of Sing with a reasonable expectation of successfully obtaining a starter culture.

10. Claims 1 – 7, 11, 17 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Rimler and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality. The method comprises

i) providing an inoculum material comprising a concentrate of starter culture cells,

ii) concentrating the inoculum material

iii) dividing the concentrated inoculum material into subsets,

iv) inoculating a subset of the inoculum material by direct, one step inoculation, into a cultivation medium

v) propagating the subset cells for a time sufficient to produce a desired amount of cells, and

vi) harvesting the propagated cells to obtain a starter culture,

wherein when steps (iv) -- (vi) are repeated with another subset of cells, the cultures have a consistent quality. The stock inoculum of step i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium or at least 10^8 CFU p gram. The subset inoculum material of step (iv) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (iv) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (iv) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells

and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Sing does not teach the method wherein the starter cells are used in the pharmaceutical industry and express a desired gene product such as an enzyme, pharmaceutically active substance, polysaccharide or amino acid. However, at the time of the claimed invention, it

would have been obvious to one of ordinary skill in the art to do so because it was a well known practice in the art at the time the invention was made. In support, Rimler teaches a method of propagating starter cells of Haemophilus in order to obtain products useful as immunological agents (abstract). Stock cultures of the bacteria are passed twice (or propagated, sub-cultured and propagated), cultured in a medium, inoculated into a starter culture tube and propagated (col.3 line 1-15) to obtain the desired pharmaceutically active substance. In further support, Lizak teaches starter cultures of fungus, Bacillus, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Moreover, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain a desired gene product via the methods of Sing.

Applicant argues that Sing is a two step inoculation of dairy products, that Sing does not provide an inoculum that is concentrated and divided before inoculating into growth mediums, that there is no motivation to supply a starter culture as claimed and that the inventive method is efficient, with a more consistent quality of cells.

However, these arguments fail to persuade because as evidenced by Sing and Kosikowski, such steps of concentrating and dividing were routinely practiced in the art at the time the claimed invention was made. Regarding applicant's claim of more a more efficient method with more, consistent quality, applicant has not provided evidence of any unexpected advantage or benefit to the method steps as claimed. Therefore, the claims stand rejected for these reasons and those above.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad
October 27, 2003

LEON B. LANKFORD, JR.
PRIMARY EXAMINER